

**REMARKS**

**I. INTRODUCTION**

Previously-submitted Figs. 4-9 have been replaced with modified Figs. 4-9, which are filed herewith on separate "Replacement" sheets. Claims 1-62 and 110-112 were previously canceled, and claims 113-139 were previously added to the originally-filed application. Claims 63, 74, 76, 78, 86-90, 93, 98, 106-109, 113, 128 and 135-139 have been amended above to clarify the subject matter recited therein. Support for such amendment(s) can be found, e.g., in paragraphs [0035], [0043], [0044], [0059], [0062] and [0070] and Fig. 8 of the published application (i.e., U.S. Patent Publication No. 2006/0155266). Claims 94 and 124 have been canceled above, without prejudice.

Accordingly, claims 63-93, 95-109, 113-123 and 125-139 are now under consideration in the present application. Provided above, please find separate "Replacement" sheets for the drawings and a claim listing indicating the current amendments to the previously-pending claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

**II. OBJECTION TO THE DRAWINGS SHOULD BE WITHDRAWN**

The Examiner objected to previously-submitted Figs. 4-9 due to minor informalities. As the Examiner shall ascertain, previously-submitted Figs. 4-9 have been replaced with modified Figs. 4-9, which are filed herewith on separate "Replacement Sheets." In particular, the enclosed modified Figs. 4-8 address various formalistic matters referred to by the Examiner in the Office Action. (See Office Action, page 2). Support for the added labels is provided in the originally-filed specification, e.g., in the paragraphs

describing each of the respective figures. Accordingly, Applicants respectfully request that the objections to Figs. 4-9 be withdrawn.

### III. **REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN**

Claims 63-89 stand rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. (See Office Action, page 3). The Examiner alleges that the recitation in claim 63 of a target area having an area of approximately  $1 \text{ cm}^2$  is unclear because it purportedly lacks positive antecedent basis in the original specification. As an initial matter, Applicants respectfully disagree, and respectfully submit that such previously-pending recitation is certainly clear and unambiguous. For example, paragraph [0059] of the published application provides the following:

“[t]he target area of the skin 714 can generally be  $1 \text{ cm}^2$  in size and each of the individual exposure areas 716 may be  $100 \text{ }\mu\text{m}$  in diameter.”

Thus, Applicants respectfully assert that such explicit disclosure provides antecedent basis for the recitation in claim 63, and that one of ordinary skill in the art would certainly know what is meant by a target area having a size that is that is approximately  $1 \text{ cm}^2$ . Nevertheless, independent claim 63 has been amended above to remove this recitation, but reserve the right to introduce such recitation in one or more claims of the present application or in any application which claims priority from the present application.

With respect to claim 74, the Examiner alleges that it is unclear what further structure is implied by reciting the effect of the radiation (i.e., that it thermally damages or ablates dermal tissue). As the Examiner shall ascertain, to expedite the prosecution of the present application but not for any reason relating to patentability thereof, claim 74 has been amended to recite that the delivery arrangement directs such radiation.

Further, to expedite the prosecution of the present application but not for any reason relating to patentability thereof, claims 78, and 98 have been amended to recite a dimension "along the surface of the skin."

Claim 94 has been canceled above without prejudice, rendering the rejection of this claim moot.

Accordingly, for at least the reasons as set forth herein above, Applicants respectfully assert that the rejection of claims 63-89 as provided herein under 35 U.S.C. §112, second paragraph should be withdrawn.

#### **IV. REJECTIONS UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN**

Claims 63, 65, 72-76, 78-88, 90, 91, 93-96, 99-108, 113, 115, 122-126 and 128-138 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 6,050,990 to Tankovich et al. (the "Tankovich Patent"). (See Office Action, page 4). Claims 63-80, 82-98, 102-109, 113-115, 122-128, and 132-139 stand rejected under 35 U.S.C. §102(e) as being allegedly anticipated by International Publication No. WO 2002/053050 (the "Altshuler Publication"). (See *id.*) Applicants respectfully assert that the Tankovich Patent and the Altshuler Publication fail to disclose the subject matter recited in amended independent claim 63, 90 and 113 and the claims which depend therefrom, for at least the reasons as set forth below. In addition, Applicants reserve the right to antedate the Altshuler Publication with respect to the claims pending in the present application, and in any application which claims priority therefrom, as applicable.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining

Procedures, §2131; *also see Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

A. Rejection based on the Tankovich Patent

The Tankovich Patent relates to a method for applying laser light to a surface region of skin tissue to produce a variety of effects such as hair removal, stimulation of hair growth, treating herpes virus, etc. The described method includes techniques for increasing the gradient of energy loss with depth in the skin to assist in forcing particles into hair ducts and other skin openings. (See, e.g., Tankovich Patent, Abstract; and col. 1, lines 53-64).

Independent claim 63, as amended herein above, relates to apparatus for treating dermatological conditions which comprises, *inter alia*:

a delivery arrangement configured to direct an electromagnetic radiation generated by an electromagnetic radiation source to at least one particular area within a target area of skin, wherein **the electromagnetic radiation is adapted to at least one of ablate or cause thermal damage to epidermal tissue and dermal tissue of the at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue ...**

Thus, amended independent claim 63 recites that **the radiation is adapted to ablate and/or cause thermal damage to epidermal tissue and dermal tissue of the at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue.**

Amended independent claims 90 and 113 relate to method and apparatus, respectively, which recite similar subject matter.

In contrast, it is respectfully asserted that the Tankovich Patent does not disclose any apparatus or method in which radiation is directed onto skin tissue such that the radiation is adapted to **ablate and/or cause thermal damage to epidermal tissue**

**and dermal tissue of at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue**, as explicitly recited in amended independent claims 63, 90 and 113 of the above-identified application. To the contrary, the Tankovich Patent describes that **only** the epidermal layer of the skin is thermally damaged, and that it is **not** preferable to burn skin, coagulate blood vessels in the dermal matrix, or even to destroy the skin pigment (i.e., melanin) located at the interface of epidermis and dermis. (See, e.g., Tankovich Patent, col. 34, lns. 37-44; col. 60, line 67-col. 61, lines 2-5; col. 62, line 64-col. 63, line 3; col. 63, lines 26-32 and 47-55; col. 64, lines 58-67; col. 64, line 64-col. 66, line 22; col. 67, lines 22-27).

Further, use of laser light within this range of wavelengths (optionally with surface cooling), as described in the Tankovich Patent, will coagulate the blood vessels at the base of the hair root, but will not destroy blood vessels below the epidermal layer of the skin. (*Id.*) Thus, the Tankovich Patent specifically avoids damaging or ablating the dermal layer, and accordingly **teaches away** from the subject matter recited in amended independent claims 63, 90 and 113 of the present application.

Accordingly, for at least the reasons presented herein above, Applicants respectfully submit that the Tankovich Patent fails to disclose the subject matter recited in amended independent claims 63, 90, and 113 of the present application. Pending claims that depend from such amended independent claims 63, 90 and 113, i.e., claims 65, 72-76, 78-88, 91, 93-96, 99-108, 115, 122-123, 125-126 and 128-138, are also not disclosed by the Tankovich Patent for at least the same reasons, and reserve the right to argue patentability of these claims separately from the patentability of amended independent

claims 63, 90 and 113. Thus, withdrawal of the rejection of these claims under 35 U.S.C. § 102(b) based on the Tankovich Patent is respectfully requested.

B. Rejection based on the Altshuler Publication

The Altshuler Publication relates to a method and apparatus for concentrating radiation in a treatment portion at a depth within a volume of skin. (See, e.g., Altshuler Publication, Abstract; page 5, lines 4-14; and Figs. 22A and 22B).

As indicated above, amended independent claims 63, 90, and 113 recite that **the radiation is adapted to ablate and/or cause thermal damage to epidermal tissue and dermal tissue of the at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue.**

In contrast, it is respectfully asserted that the Altshuler Publication does not disclose, much less teach or suggest any apparatus or method in which radiation is directed onto skin tissue such that the radiation is adapted to **ablate and/or cause thermal damage to epidermal tissue and dermal tissue of at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue**, as explicitly recited in amended independent claims 63, 90 and 113 of the above-identified application. Instead, the Altshuler Publication describes method and apparatus for focusing radiation into three-dimensional treatment portions **within** the skin tissue (i.e., underneath the skin tissue), and avoids damaging the entire depth of the epidermal tissue from the skin. (See, e.g., Altshuler Publication, page 10, lines 15-20; page 12, lines 4-6; page 11, line 24 to page 12, line 6; page 15, lines 4-7 and 19; and Figs. 2-6A and 22A).

Accordingly, , for at least the reasons presented herein above, Applicants respectfully submit that the Altshuler Publication fails to disclose, much less teach or suggest the subject matter recited in amended independent claims 63, 90, and 113, and in the pending claims that depend therefrom. Pending claims that depend from such amended independent claims 63, 90 and 113, *i.e.*, dependent claims 64-80, 82-89, 91-98, 102-109, 114-115, 122-123, 125-128 and 132-139, are also not disclosed by the Tankovich Patent for at least the same reasons, and reserve the right to argue patentability of these claims separately from the patentability of amended independent claims 63, 90 and 113. Thus, withdrawal of the rejection of these claims under 35 U.S.C. § 102(e) is respectfully requested.

In addition, as provided herein above, Applicants reserve the right to antedate the Altshuler Publication with respect to the claims pending in the present application, and in any application which claims priority therefrom, as applicable.

**V. REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN**

Claims 63-109 and 113-139 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Altshuler Publication, in combination with U.S. Patent No. 6,517,532 to Altshuler et al. (the "Altshuler Patent"). (See Office Action, page 5). Applicants respectfully assert that the alleged combination of the Altshuler Publication with the Altshuler Patent fails to teach or suggest the subject matter recited in amended independent claims 63, 90, and 113 and the claims which depend therefrom, for at least the reasons as set forth below. In addition, Applicants reserve the right to antedate the Altshuler Publication and the Altshuler Patent with respect to the claims pending in the present application, and in any application which claims priority therefrom, as applicable.

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*,



No. 2006-1192, 2007 U.S. App. LEXIS 23969, \*21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Altshuler Patent relates to an apparatus for delivering light energy that includes a cooled, transparent layer. (See, e.g., Altshuler Patent, Abstract, col. 2, lines 15-33). However, the Altshuler Patent fails to cure at least the deficiencies of the Altshuler Publication to teach or suggest apparatus or method in which radiation is directed onto skin tissue such that the radiation is adapted to **ablate and/or cause thermal damage to epidermal tissue and dermal tissue of at least one particular area surface of the skin through an entire depth of the epidermal tissue and to at least a particular depth within the dermal tissue**, as explicitly recited in amended independent claims 63, 90 and 113 of the above-identified application.

Accordingly, for at least the reasons presented herein above, Applicants respectfully submit that the alleged combination of the Altshuler Publication and the Altshuler Patent fail to teach or suggest the subject matter recited in amended independent claims 63, 90, and 113. Pending claims that depend from such amended independent claims 63, 90 and 113, i.e., dependent claims 64-89, 91-109, 114-123 and 125-139, are also not taught or suggested by such alleged combination, for at least the same reasons, and reserve the right to argue patentability of these claims separately from the patentability of amended independent claims 63, 90 and 113. Thus, withdrawal of the rejection of these claims under 35 U.S.C. § 103(a) is respectfully requested.

In addition, as provided herein above, Applicants reserve the right to antedate the Altshuler Publication and the Altshuler Patent with respect to the claims pending in the present application, and in any application which claims priority therefrom, as applicable.

**VI. CONCLUSION**

In light of the foregoing, Applicants respectfully submit that all arguments raised in the Office Action have been addressed and that all pending claims 63-93, 95-109, 113-123, and 125-139 are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

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